

Certificate of Analysis

Productname: Bacitracinum micronisatum
Number of analysis/Inspection Code: 1 / KEUR-185515B
Batchnumber: 20E14-F01-373028
Reference code / No.: 3697 / C2280138
Analysed according to: PHEUR10.2+

Tests	Requirement	Result	Unit	Standard remark
Fermentation	Conform	Conform		Data producer
Particle size	99% <50 µm	Conform		Microscopy
Identification B	Conform	Conform		Composition
Identification C	Conform	Conform		
Appearance of solution	Clear	Conform		1%m/V
Absorbance at 420 nm	<=0,45	0,12		
pH	6,0 - 7,0	6,3		1%m/V
Composition	Conform	Conform		HPLC
Bacitracin A	>=45,0	53,0	%	
Sum of bacitracins A, B1, B2 and B3	>=77,0	80,8	%	
Related substances	Conform	Conform		HPLC
Sum of impurities L and N	<=8,0	5,5	%	
Impurity E	<=4,0	0,8	%	
Impurity A	<=3,5	2,2	%	
Impurity B	<=3,0	1,8	%	
Impurity M	<=3,0	0,8	%	
Impurity C	<=2,5	1,5	%	
Sum of impurities O,P and Q	<=2,5	0,9	%	
Sum impurities F and G	<=2,0	<0,25	%	
Impurity H	<=1,0	<0,25	%	
Any other impurity	<=2,0	1,4	%	
Total impurities	<=23,0	19,2	%	
Loss on drying	<=5,0	0,3	%	3 h 60°C vacuum
Sulphated ash	<=1,0	0,1	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Bacitracin	>=60	76	IU/mg	Dried; data producer
Assay Bacitracin		75	IU/mg	Not dried; data producer
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer



Analysis performed by the authorized laboratory Pharma Cosmetic Polen.

Release:

Paul Hofman

Pharmacist - Qualified Person

09/07/20

Expiration: 12-2023

Conclusion: APPROVED

This document has been produced electronically from our quality system and is valid without signature.